

Propofol requirement for insertion of I-gel versus laryngeal mask airway: A comparative dose finding study using Dixon's up-and-down method

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Abstract

Background and Aims: Propofol is the drug of choice when used as sole anesthetic agent for placement of supraglottic airway devices. We aimed to find and compare the propofol dose required for smooth first attempt insertion of I-gel versus the classic laryngeal mask airway (cLMA) using Dixon's up-and-down method.

Material and Methods: Prospective randomized controlled trial ($n=60$) was planned. I-gel or cLMA was inserted 60 s after propofol injection whose dose was calculated based on previous patients response as per Dixon's up-and-down method. Propofol requirements for successful placement of devices was noted and compared. Difference between the groups was measured by ANOVA. A $P < 0.05$ was considered as statistically significant.

Results: Significantly lower ($P < 0.001$) propofol dose was required for I-gel (2.02 ± 0.26 mg/kg) insertion than cLMA (2.70 ± 0.28 mg/kg).

Conclusions: I-gel requires significantly lower dose of propofol for insertion when compared to cLMA.

Key words: Classic laryngeal mask airway, Dixon's up-and-down method, I-gel, propofol

Introduction

Propofol as sole anesthetic agent is extensively used for placement of supraglottic airway devices (SGADs) such as classic laryngeal mask airway (cLMA), I-gel, proseal LMA, etc. Newer SGADs like proseal LMA, I-gel^[1,2] etc., are rapidly replacing endotracheal intubation for maintenance of airway in short surgical procedures.

The insertion of these devices requires sufficient depth of anesthesia for the relaxation of jaw muscles and suppression of upper airway reflexes such as coughing, gagging and laryngospasm.^[3] Propofol is considered as the superior

intravenous (I.V) induction agent in achieving the optimum conditions for LMA insertion, compared with thiopentone and other I.V induction agents.^[4] Limited number of studies are available on the anesthetic requirement needed for newer SGADs, in comparison to the plethora of studies on dose requirements for cLMA.^[5-9]

Dixon's up-and-down method^[10] has been successfully used previously to determine the dose of propofol required for insertion of supraglottic devices. A minimum of 6 cross-over points is needed for this method to be used effectively.

Our primary aim was to find the dose of propofol required for smooth insertion of I-gel in the first attempt and to compare it with the cLMA using Dixon's up-and down method. Hemodynamic stability with these doses and complications, if any were studied as a secondary objective. We postulated that I-gel produces less stimulation to the airway and thus would require lesser dose of propofol than LMA.

Material and Methods

The study was carried out after approval of the Institutional Ethics Committee. The written informed consent was obtained from 60 American Society of Anesthesiologists (ASA) grade

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I and II patients between 18 and 65 years scheduled for elective surgery of <2 h. Patients were randomly assigned into two groups by computer generated randomized table that consisted of Group L: LMA insertion with propofol and Group I: I-gel insertion with propofol.

A thorough preanesthetic evaluation was done the day prior to surgery. Nonconsenting patients, pregnant women, lactating mothers, patients with unstable medical conditions, with known allergy to propofol and patients with difficult airway were excluded.

On arrival in the operation theater, monitoring was commenced with noninvasive arterial blood pressure, electrocardiogram (ECG) monitor and pulse oximeter. I.V access was secured with a 20 G cannula. Patients were premedicated with injection glycopyrrolate 0.004 mg/kg I.V, injection ondansetron 0.08 mg/kg I.V, injection ranitidine 1 mg/kg I.V, injection fentanyl 2 ug/kg I.V, injection midazolam 0.02 mg/kg I.V. Patients were preoxygenated for 5 min and Ringer's lactate 5 ml/kg was administered in this period.

Patients then received predetermined dose of propofol intravenously beginning with 2 mg/kg for the first patient in each group given over 30 s. I-gel or LMA was inserted 60 s after propofol injection. Patient's response was assessed as "movement" or "no movement."

The term "movement" was defined as resistance in mouth opening, gross purposeful movement, coughing, straining or laryngospasm occurring after insertion of the device or during airway manipulations before an effective airway is established.

The term "no movement" was defined as the absence of bucking or gross purposeful movements after insertion of the device until an effective airway is established.

When a patient's response was "movement," additional bolus doses of propofol 0.5 mg/kg were given and insertion reattempted at 30 s intervals until insertion was successful or 3 attempts were reached. The type of movement seen was recorded. Both the devices were inserted according to manufacturer's instructions and literature. Device was connected to the breathing system and bilateral, and equal air entry was confirmed by symmetrical chest movements and auscultation. Adequate airway without leak was confirmed by capnography. In the case of failure to insert device in three attempts or any complications like desaturation, severe hypotension requiring endotracheal intubation, patient was oxygenated with 100% oxygen, succinyl choline 2 mg/kg was administered and trachea was intubated using cuffed endotracheal tube of appropriate size.

Hemodynamic parameters like pulse, blood pressure and ECG changes and respiratory parameters like SpO₂ and end tidal CO₂ were noted when the patient was taken inside the operation theatre (0 min i.e., baseline), after 3 min of premedication, at the start of propofol bolus and every minute for next 5 min thereafter. All the patients were observed for adverse events like bronchospasm, laryngospasm during insertion, maintenance or after removal of the device.

The device was removed at the end of surgery after patients were conscious, obeying verbal commands. Presence of blood, secretions, etc. if any, was noted. Postoperatively each patient was followed for 24 h to note the incidence of sore throat.

The doses of propofol for each patient were predetermined by modifications of Dixon's up-and-down method. In each group, the first patient received a dose of 2 mg/kg. For the next patient, the dose of propofol was increased by 0.5 mg/kg if the response in preceding patient was judged as "movement" or decreased by 0.5 mg/kg if response in preceding patient was "no movement." The step size that is, 0.5 mg/kg approximates the estimated standard deviation derived from previous studies^[11,12] Hence, each patient in the study group received a predetermined dose of propofol depending upon previous patient's response.

Response of each patient with the dose used, was plotted on a graph, with the patient's response on X axis and dosage in mg/kg on Y axis. Propofol dose was then determined by calculating the midpoint dose of all independent pairs of patients using a cross-over technique that is "movement" to "no movement." The ED₅₀ for I-gel and LMA groups were defined as the average of the cross-over midpoints in each group. For the successful use of this method, we needed a minimum of 6 cross-over midpoints in each group. We studied 30 patients in each group and obtained 10-11 cross-over midpoints in both the groups.

Statistical analysis

With the appropriate starting dose, Dixon's up-and-down method requires a minimum of 6 cross-over points in each group for estimation of ED₅₀. Assuming a positive result with the starting dose, a minimum of 13 patients would have to be recruited in each group. The starting dose has to be the minimum dose expected to result in a positive response that is, no movement to insertion of the device in our case. Based on previous studies^[11,12] we started with a dose of 2 mg/kg of propofol for both devices. The step size, that is, 0.5 mg/kg, approximates to the estimated standard deviation derived from previous studies.^[11,12] Given the less stimulatory nature of I-gel on the airway^[13] and based on our pilot study, we hypothesised

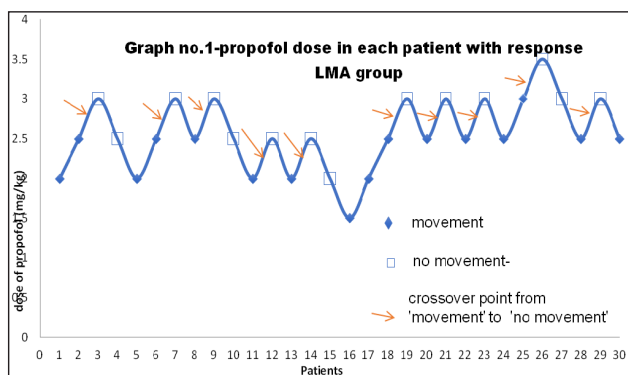
that I-gel would require at least 0.5 mg/kg less propofol as compared to cLMA. To detect a difference of 0.5 mg/kg dose requirement of propofol (power 90%, alpha error 0.05 and beta error 0.10 with a standard deviation of 0.5 mg/kg) a minimum of 22 patients were required in each group. Data was analyzed using software version SPSS 12.0 (SPSS Inc., 233 South Wacker Drive, 11th Floor, Chicago, IL 60606-6412). For each parameter mean and standard deviation were calculated to estimate the significance. Difference between the groups was measured by ANOVA test. For other categorical data like adverse events, Chi-square test was used. In this study for all results $P < 0.05$ was considered as statistically significant.

Results

There were no significant differences between both groups with respect to demographic variables [Table 1].

Graphs 1 and 2 show propofol dose given to each patient in particular study group and response to device insertion that is, "movement" and "no movement" at corresponding propofol dose. The cross-over points from movement to no movement are highlighted using arrows in graphs. ED₅₀ of propofol, which was calculated as the average of the cross-over midpoints in each group was significantly higher in the LMA group 2.70 ± 0.28 mg/kg (mean ± standard deviation [SD]) when compared to I-gel group 2.02 ± 0.26 mg/kg (mean ± SD) ($P < 0.001$) [Table 2].

The arterial pressure and heart rate were comparable between the two groups [Graph 3a-c]. Peripheral limb movements and resistance to mouth opening were the most common types of movement noted in both the groups, which were overcome by using additional dose of propofol. Hiccups were noticed in one patient in I-gel group, which could be treated by additional propofol boluses [Table 3].



Graph 1: Propofol dose in each patient with response laryngeal mask airway group

Adverse events such as bronchospasm, laryngospasm, hypotension, regurgitation and aspiration were not observed in any of the groups. Four patients in LMA group complained of sore throat, which was statistically more significant when compared to I-gel group where no patient had sore throat [Table 4].

Discussion

The optimum dose of propofol required to insert SGADs, without using neuromuscular blockers, while providing hemodynamic stability remains a challenge. The dose requirement can also influence the choice of SGAD especially where hemodynamic stability is desired. The major finding of this study was that the propofol requirement for smooth insertion of the I-gel was significantly less ($P < 0.001$) [Table 2] than that of LMA insertion. This was expected because of the less stimulatory effect of the I-gel on the airway due to its composition of soft thermoelastic polymer.

Table 1: Demographical data

Parameters	I-gel	LMA
	Mean ± SD	Mean ± SD
Age (years) [@]	33.70 ± 11.03	37.70 ± 8.13
Weight (kg) [@]	48.10 ± 6.83	52.03 ± 7.74
Sex (male: female) [#]	14:16	16:14

[@]By Student's t-test; $P > 0.05$ not significant, [#]By Chi-square test. SD = Standard deviation, LMA = Laryngeal mask airway

Table 2: ED₅₀ of propofol by Dixon's up-and-down method

Groups	ED ₅₀ (mg/kg)
I-gel	2.02 ± 0.26
LMA	2.70 ± 0.28

By Student's t-test; $P < 0.001$. LMA = Laryngeal mask airway, ED = Effective dose

Table 3: Profile of response to device insertion

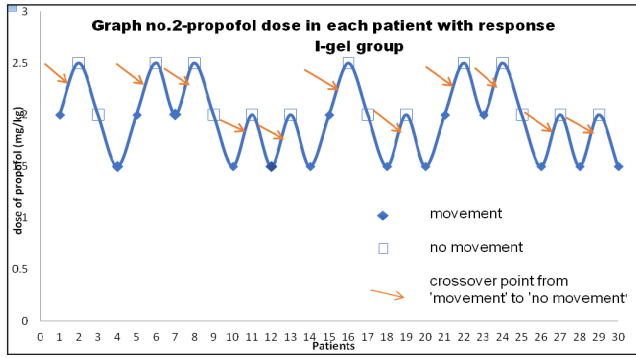
Response	I-gel	LMA
	Number (%)	Number (%)
Resistance to mouth opening	06 (20)	08 (26.6)
Movement of limbs	14 (46.7)	13 (43.3)
Other gross movement	—	—
Coughing, gagging	—	—
Hiccups	01 (3.3)	—

By Chi-square test; $P > 0.05$ not significant. LMA = Laryngeal mask airway

Table 4: Profile of adverse events

Events	I-gel	LMA
	Number (%)	Number (%)
Bronchospasm	—	—
Laryngospasm	—	—
Hypotension	—	—
Regurgitation, aspiration	—	—
Sore throat	—	4 (13.3)

By Chi-square test; $P = 0.38$ significant. LMA = Laryngeal mask airway



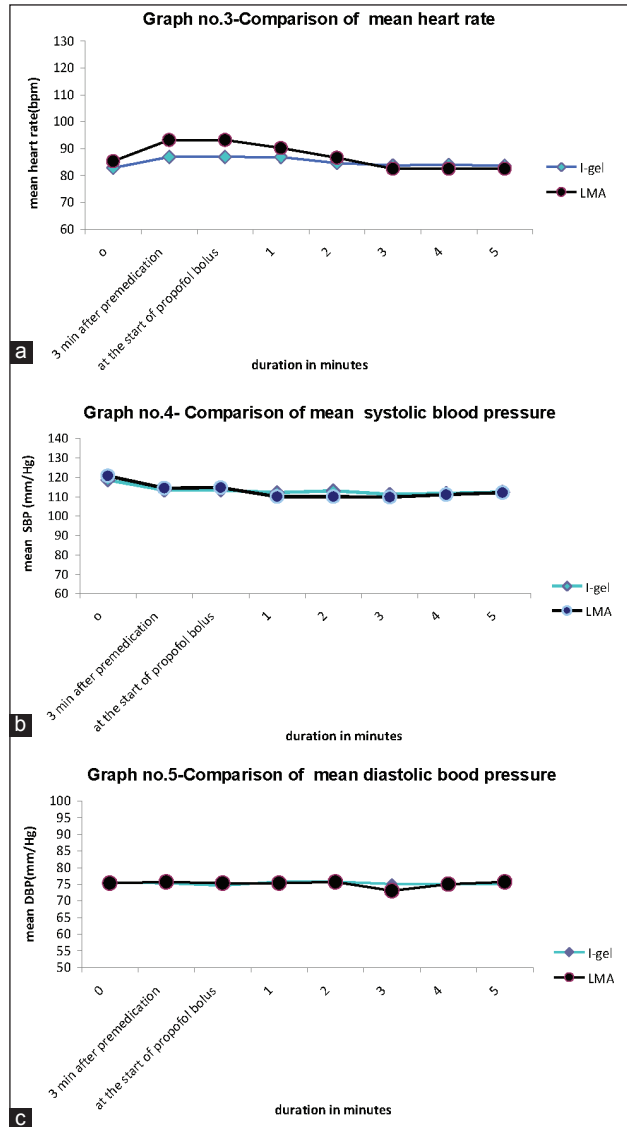
Graph 2: Propofol dose in each patient with response I-gel group

Amr and Amin^[5] found that use of propofol at 2.5 mg/kg produced comparable insertion conditions for I-gel compared with thiopentone sodium (7 mg/kg). They used fixed dose of propofol 2.5 mg/kg for every patients and premedication was not given unlike our study where we used Dixon's up-and-down method along with fentanyl 2 microg/kg and midazolam 0.02 mg/kg as premedication.

Our study estimated the ED₅₀ of propofol required for LMA insertion to be 2.70 ± 0.28 mg/kg. This is higher than the study by Tanaka and Nishikawa^[11] who found propofol requirements after fentanyl for LMA insertion to be 1.42 ± 0.26 (1.15-1.69) mg/kg. Also in the study conducted by Burlacu *et al.*^[12] propofol requirement was 2.33 ± 0.37 mg/kg, as they used alfentanil 5 microg/kg for co-induction unlike our study, where we used fentanyl 2 microg/kg. Hui *et al.*^[14] reported that co-administration of alfentanil-propofol provided better insertion condition for LMA than fentanyl-propofol. Also our criterion of smooth insertion (i.e., the definition of 'no movement') may have been relatively strict compared to study conducted by Tanaka and Nishikawa.^[11]

The statistically significant difference in the requirements of propofol for the placement of the I-gel and LMA suggests that upper airway stimulation is lesser during insertion of I-gel. It is possible that the potent inhibitory effect of fentanyl on the upper airway reflexes may have masked the different airway stimulating effects of the two devices. Tanaka and Nishikawa^[11] using similar study design demonstrated the same masking effect of co-induction when using fentanyl.

In our study, there was neither any significant fall or increase in systolic and diastolic blood pressure and heart rate in both the groups. These findings were almost similar to study by Helmy *et al.*^[15] where they found no statistical significant difference between both I-gel and LMA regarding hemodynamic parameters. Shin *et al.*^[16] also found no difference in hemodynamic data immediately after the insertion of I-gel, Proseal LMA and classic LMA.



Graph 3: (a) Comparison of mean heart rate. (b) Comparison of mean systolic blood pressure. (c) Comparison of mean diastolic blood pressure

Propofol reduces arterial blood pressure due to reduction in sympathetic tone and direct venodilator effect. As the patients in the LMA group received higher mean dosage of propofol, a steeper fall in blood pressure was expected. However the hemodynamic stability observed in our study can be contributed to the hypotension produced by propofol, which offsetted the pressor responses of LMA.

None of the patients either in LMA or I-gel group developed coughing, gagging or laryngospasm which correlates with the study done by Gatward *et al.*^[17] and Kannaujia *et al.*^[18] This may be due to the use of Dixon's method for dose choice, where higher dose was used if previous patient had movement with lower dose instead of using a fixed dose for whole group. This method minimized the chances of oropharyngeal and laryngeal stimulation at lighter plane of anesthesia. We cannot exclude

the possibility of potent inhibitory effect of fentanyl on upper airway reflexes.

None of the patients of both study groups had obvious aspiration or regurgitation similar to study done by Kannaujia *et al.*^[18] and Brimacombe *et al.*^[19] However rigorous criteria like pH examination were not performed in our study.

Greenberg *et al.*^[20] observed that immediate postoperative sore throat was complained by 33 patients in patients with LMA insertion. In our study, four patients in LMA group had immediate postoperative sore throat as compared to none in I-gel group which correlates with the study by Shin *et al.*^[16] This could be because of the soft gel like noninflatable cuff of I-gel, which causes minimal tissue compression and thus maintains blood flow to the laryngeal and perilaryngeal framework, whereas cuff of LMA can absorb anesthetic gases leading to increased mucosal pressure.

However, these results need to be interpreted as per the limitations of our protocol. The dose of propofol required has been calculated by use of Dixon's up-and-down method where we obtained 11 cross-over points against a minimum of 6 which is a valid technique. Also the results for hemodynamic effects and incidence of sore throat need to be validated with a study of larger number of patients. We studied only low risk patients (ASA I or II) who had normal airways and were not obese. Also comparing the performance of the likely competitors of the I-gel like ProSeal LMA would help in clarifying the choice of SGADs.

Conclusions

Propofol requirement for successful smooth insertion of I-gel was significantly less ($P = 0.0001$) compared to classic LMA. The postoperative complications are not significantly different among I-gel and LMA patients except for overall low incidence (13.3%) of sore throat seen only in the LMA group.

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